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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/853,188

05/09/2001

Ilham Mohamed Saleh Saeed Abuljadayel

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EXAMINER

CANELLA, KAREN A

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

05/04/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/853,188

Applicant(s)

ABULJADAYEL, ILHAM
MOHAMED SALEH SAEED

Examiner

Karen A. Canella

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-3,5,7,11-13,15,17,19-41,101 and 104-107 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1-3,5,7,11-13,15,17,19-41,101 and 104-107 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/15/01</u> | 6) <input type="checkbox"/> Other: ____ |

Art Unit: 1643

DETAILED ACTION

Claims 19-27, 101 and 106 have been amended. Claims 42-100, remain withdrawn from consideration. Claims 1-3, 5, 7, 11-13, 15, 17, 19-101 and 104-107 are pending. Claims 1-3, 5, 7, 11-13, 15, 17, 19-41, 101 and 104-107 are under consideration.

It is restated that the instant invention will be given priority only to UK application 0101315.0, filed January 18, 2001.

Claims 39 remains objected to for being dependent in part on canceled claim 4.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5, 7, 11, 13, 15, 17, 19-41, 101, 104-107 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for device comprising a means for introducing into a chamber an agent which is an anti-MHC antibody which operable engages the MHC receptors in a population of committed cells which are hematopoietic cells and results in an increase in the relative number of undifferentiated cells, does not reasonably provide enablement for an agent which operably engages the MHC which is any other substance, or a starting cell population which is of non-hematopoietic origin. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 1-3, 5, 7, 11, 13, 15, 17, 19, 20, 23-37, 39-41 encompass device for increase the relative number of undifferentiated cells in any cell population. The specification provides no objective evidence that a cell population comprising committed cells from any other population than hematopoietic cells can be used to provide an altered cell population comprising an increased number of undifferentiated cells. The state of the art is unreliable with respect to the "plasticity" of hematopoietic cells. for instance Almedida-Porada et al (Reviews in Clinical and

Art Unit: 1643

Experimental Hematology, 2001 Mar, Vol. 5, pp. 26-41) summarize experimental findings that support hematopoietic cell plasticity. However, Horwitz (Current Opinion in Pediatrics, 2003, Vol. 15, pp. 32-37) teaches that hematopoietic stem cell activity has yet to be rigorously proven. It is concluded that the state of the art is not mature with respect to adult stem cell plasticity. The specification provides evidence of obtaining a population comprising more undifferentiated cells after contact of a buffy coat blood sample with antibodies that engage the MHC receptor. Because the art is unreliable, there is no adequate nexus between the obtaining a population enriched in undifferentiated cells by treatment of any population comprising committed cells. Because of the unreliability in the art and lack of objective evidence in the specification one of skill in the art would be subject to undue experimentation in order to use the claimed device to make populations of less differentiated cells from starting population of committed cells which were not hematopoietic cells.

Claims 1, 2, 3, 5, 7, 11, 13, 15, 17, 19-34, 37-41, 100, 101 and 104-107 encompass agents which are broader in scope than antibodies which bind to the MHC receptor. It is noted that claim 27, requiring an agent which engages a receptor that mediates capture, recognition or presentation of an antigen at the surface of the committed cell encompasses receptors which are not limited to the MHC receptor, such as the Fc receptor on dendritic cells, said receptor mediating the capture of antibody-antigen complexes and the presentation of said antigen on the surface of the mature dendritic cell. The specification provides no evidence that an agent, such as an anti-Fc antibody could induce the enrichment of undifferentiated cells in a population comprising committed cells. Because of the unreliability in the art as stated in the paragraph above and lack of objective evidence in the specification one of skill in the art would be subject to undue experimentation in order to use the claimed device to make populations of less differentiated cells from starting population of committed cells using devices which comprises a means for introducing a generic "agent" into a chamber including committed cells.

All other rejections and objections as set forth in the previous Office action are withdrawn.

All claims are rejected.

Art Unit: 1643


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen A. Canella, Ph.D.

4/29/2007


KARENA. CANELLA PH.D
PRIMARY EXAMINER